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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,845	09/24/1999	MARIN JANUSZ	AAT-11612	1703

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EXAMINER	
TELLER, ROY R	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/269,845	Applicant(s) JANUSZ ET AL.	
	Examiner Roy Teller	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-7,13-17,24,26-36,38,40,41,46,47 and 53-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7,13-17,24,26-36,38,40,41,46,47 and 53-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9 & 20* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's response to previous office action was found persuasive. The 101 rejection and 112/2nd rejection are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-7,13-17,24,26-36,38,40-41,46-47,53-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for colostrinin useage as a modest cytokine inducer in human leukocytes does not reasonably provide enablement for treatment of chronic disorders of the central nervous system with colostrinin.The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;

2) the breadth of the claims;

3) the predictability or unpredictability of the art;

4) the amount of direction or guidance presented;

5) the presence or absence of working examples;

6) the quantity of experimentation necessary;

7) the state of the prior art; and

8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

1) the nature of the invention;

Colostrinin is used as a medicament and treatment for chronic disorders of the central nervous system, neurological and/or mental disorders, dementia and/or neurodegenerative diseases, Alzheimer's disease and/or motor neuron disease, psychosis and/or neurosis.

2) the breadth of the claims;

Chronic disorders of the central nervous system are not limited to treatment or condition, an example is permanent spinal cord injury, a chronic, non-fixable central nervous system disorder. Other examples of chronic disorders of the central nervous system are multiple sclerosis, amyotrophic lateral sclerosis, and sensory recognition problems: sight, feel, paralysis.

3) the predictability or unpredictability of the art;

The specification has shown an immunomodulation effect occurred when colostrinin was administered to mice and humans. The specification did not show an effect and/or treatment for chronic disorders of the central nervous system. The art is still unpredictable in light of Kruzel's (Journal of Molecular Neuroscience, 2001, 17, pp.379-389) abstract which stated "... it is hoped that the beneficial use of colostrinin in Alzheimer's disease...will revive interest in its clinical application for treatment and/or prophylaxis of many age-related disorders."

4) the amount of direction or guidance presented;

The specification showed some guidance with regards to an immunomodulation effect when colostrinin was administered to mice and humans. The specification gave little guidance or direction in the treatment of chronic disorders of the central nervous system. In example IX, pages 19-20 of the specification, a method of treatment of disorders of the central nervous system was investigated. It was found that colostrinin treatment induced a state of hyporeactivity or tolerance. In example X, page 21 of the specification, a method of treatment of disorders of the central nervous system was investigated. It was found that colostrinin treatment induced a state of hyporeactivity or tolerance. Beyond this, no treatment of chronic disorders of the central nervous system occurred.

5) the presence or absence of working examples;

The specification gave examples of inducted cytokines with colostrinin *in vitro* on blood taken from healthy and sick volunteers. Patients with early stages of Alzhiemer's disease were given Colostrinin/NP tablets in which improved contact and uplift of mood was observed. The specification did not give examples for treatment of chronic disorders of the central nervous system. A chronic disorder of the central nervous system, e.g., Alzheimer's disease, can only be diagnosed post-mortem with the dissection of the brain. The examples IX and X, pages 19-21 of the specification, are not adequate working examples for the treatment of chronic disorders of the central nervous system, such as Alzheimer's disease.

6) the quantity of experimentation necessary;

Undue experimentation would be necessary in order to determine a treatment for chronic disorders of the central nervous system involving colostrinin.

7) the state of the prior art;

In Inglot (Archivum Immunologiae et Therapiae Experimentalis, 1996, 44, 215-224) colostrinie is referred to as a modest cytokine inducer in human leukocytes. In Janusz (Archivum Immunologiae et Therapiae Experimentalis, 1993, 41, 275-279) ovine colostrum is an immunomodulatory peptide. Treatment for chronic disorders of the central nervous system were not investigated. The prior art cited above does not teach of a treatment for chronic disorders of the central nervous system, therefore, undue experimentation would be necessary to determine a treatment for chronic disorders of the central nervous system involving colostrinin.

8) the relative skill of those skilled in the art;

In view of the discussion of each of the preceding factors the level of skill in this art is high and is at least that of a PhD. with several years of experience in the art. As the cited art would point to, even with this level of skill in the art, predictability of the results is not in invariable.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Claim Rejections - 35 USC § 103

Applicant's arguments for the 103 rejection were found unpersuasive, 103 rejection is upheld.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703)305-4243. The examiner can normally be reached on Monday-Friday from 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923.The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

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Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER